IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF SALIL KHANDWALA, M.D.

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motions they filed in relation to the general-causation opinions of Salil Khandwala, M.D., in Waves 1 and 2, Dkt. 2003, 2004, 2469, 2470. The Court has ruled on Plaintiffs' Wave 1 motion, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., No. 2327, 2016 WL 4599218, at *3 (S.D.W. Va. Sept. 2, 2016), but the Wave 2 motion remains pending. Defendants Ethicon, Inc., Johnson & Johnson and, where applicable, Ethicon LLC (Ethicon) respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed below and in accordance with this Court's September 2, 2016 Memorandum Opinion and Order.

Dr. Khandwala is board certified in Obstetrics and Gynecology, with a specialty certification in Female Pelvic Medicine and Reconstructive Surgery. He has performed over 2,000 surgical implantations of mid-urethral slings, has been treating pelvic organ prolapse (POP)—including with synthetic mesh systems—since 1997, and has performed numerous mesh revision surgeries. He has designed and participated in clinical trials involving mesh sling implants and other pelvic reconstructions. He has published in the fields of urinary incontinence and genital organ prolapse, and has broad teaching experience in these fields.

Despite Dr. Khandwala's extensive qualifications, Plaintiffs seek to exclude his opinions about: (1) risk information in the Instructions for Use (IFUs) and Patient Brochures for the TVT, TVT-O, and TVT-S; (2) biocompatibility and mesh physical properties, including degradation, shrinkage, contraction, particle loss, and porosity; and (3) design of the TVT, TVT-O, and TVT-S.[1] Plaintiffs' motion should be denied because:

- **Dr. Khandwala is qualified to testify about risks of implanting mesh and the common knowledge of physicians regarding risks, and fully supported his opinions with a reliable methodology**. Dr. Khandwala is qualified to offer opinions about whether there is valid scientific evidence for alleged risks identified by Plaintiffs' expert, and whether such alleged risks are commonly known among pelvic floor surgeons. Further, his opinions are supported by a reliable methodology because they are based on his extensive experience, review of the medical literature, and discussions with colleagues.

- **Dr. Khandwala is qualified to offer opinions on biocompatibility and mesh physical characteristics, and his opinions are supported by a reliable basis**. This Court has found Dr. Khandwala and numerous similarly experienced surgeons qualified to testify on these topics. Also, review of dozens of high-quality scientific articles, and statements of leading surgical associations constitutes a reliable methodology to support his opinions.

- **Dr. Khandwala is qualified to testify regarding the design of the TVT, TVT-O, and TVT-Secur**. In addition to his clinical experience and comprehensive review of the medical literature, Dr. Khandwala has relevant design-related experience to support his opinions on these topics.

Plaintiffs' challenges to Dr. Khandwala's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

[1] Plaintiffs have incorporated by reference their *Daubert* challenges to Dr. Khandwala's opinions filed in Waves 1 and 2 Pls.' Notice of Adoption (Dkt. 2781) at 1 (incorporating Plaintiffs' Wave 1 Khandwala motion and memorandum, Dkts. 2003 and 2004, respectively, and Plaintiffs' Wave 2 amended motion and memorandum, Dkts. 2469 and 2470, respectively). In response, Defendants incorporate by reference their Opposition to Plaintiffs' Wave 1 motion (Dkt. 2175).

ARGUMENTS AND AUTHORITIES

I. Dr. Khandwala's Opinions About Potential Risks of Implanting Mesh and the Common Knowledge of Physicians Regarding Risks Are Admissible.

Dr. Khandwala seeks to testify about the potential risks of the TVT, TVT-O, and TVT-Secur—both those risks that attend *any* pelvic reconstruction (of which surgeons are aware) and those that are specific or unique to Ethicon's TVT products based on valid scientific support. Based on his analysis, Dr. Khandwala proposes to testify that the alleged risks identified by Plaintiffs' experts are generally known to pelvic-floor surgeons or are not supported by valid scientific evidence. Dr. Khandwala is qualified to provide this opinion and his methodology is reliable.

A. Dr. Khandwala Is Qualified to Offer These Opinions.

Dr. Khandwala's proposed testimony is consistent with this Court's orders. As this Court has determined, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Sci. Corp.*, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015). Further, the Court has expressed no opinion about expert testimony regarding "whether certain risks were common knowledge in the medical community," and therefore has not precluded this expert testimony. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) ("The plaintiffs' Motion focuses on whether Dr. Woods is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same, with respect to Dr. Drolet); *In re: Ethicon, Inc. Pelvic Repair*

Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Serels); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Sepulveda-Toro); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493666, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Toglia); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Pramudji).

Dr. Khandwala is qualified to testify regarding risks that are within the common knowledge of surgeons who perform mesh implantations. Dr. Khandwala has been teaching and practicing in the fields of urogynecology and reconstructive pelvic surgery for almost 20 years. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 2–3. He is board certified in Obstetrics and Gynecology, and was among the first surgeons certified in Female Pelvic Medicine and Reconstructive Surgery (FPMRS), a specialty approved in the spring of 2011. *Id.* at 4. As part of the NIH's Urinary Incontinence Treatment and Pelvic Floor Disorders Networks, he has designed and participated in landmark clinical trials evaluating sling procedures and other pelvic reconstructions. *Id.* at 3–4. He has performed over 2,000 surgical implantations of mid-urethral slings—roughly 800 of which involved Ethicon's TVT, TVT-O, or TVT-Secur products. *Id.* at 3. He has been performing POP reconstructions, using methods ranging from native tissue repairs to implantation of synthetic mesh systems from Ethicon and other manufacturers, since 1997. *Id.* He has also performed roughly 25 mesh revision surgeries. Ex. D to Am. Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 70:21–71:2.

Drawing on this experience, Dr. Khandwala has long trained other surgeons in the implantation of synthetic mesh slings and related procedures. In particular, he has trained over 100 OB/GYN residents, as well as two fellows in the new FPMRS specialty, and teaches related courses both domestically and internationally. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 4. He also has trained pelvic reconstruction surgeons in the proper procedures for implanting Ethicon synthetic mesh products through proctorships at his facility and others, and by conducting cadaver labs. Ex. 1, Khandwala 7/8/16 Dep. Tr. 28:15–29:14. He has led discussion groups at annual meetings and served on boards of Ethicon's main proctors available to answer questions regarding proper implantation techniques from surgeons in the field. *Id*. 102:16–104:3.

As a practicing surgeon who went through years of medical training, has extensive clinical experience with pelvic floor surgeries, teaches other physicians about synthetic mesh slings and related procedures, and keeps up with the medical literature, Dr. Khandwala is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic floor surgeries. Indeed, only a physician with such training and experience *could* testify as to common knowledge of surgeons who perform pelvic surgeries.[2]

[2] This testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A, cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

B. Dr. Khandwala's Opinions Are Supported by a Reliable Methodology.

Dr. Khandwala concluded that the alleged risks identified by Plaintiffs' experts involve risks of which pelvic-floor surgeons were already aware or are alleged risks without valid scientific support. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 32-35. Specifically, with respect to pelvic pain, dyspareunia, scarring, and vaginal shape changes, Dr. Khandwala testified that"[a]ll surgeons performing vaginal surgery, including the TVT or TVT-O, are expected to be well aware of these known potential surgical complications." *Id*. at 34; *see also id*. ("[t]he incidence of dyspareunia due to the TVT and TVT-O sling is less than 1%" (citing Tommaselli 2015)). Dr. Khandwala also testified that surgeons in this field are commonly aware "that revision might be necessary, that a permanent implant may be difficult to remove and that revision might not alleviate symptoms." *Id.*

In support of his opinions, Dr. Khandwala relied on his experience performing hundreds of TVT procedures and treatment of patients who had slings implanted by other doctors, his outcome analysis of the procedures in clinical trials, his participation in and teaching of cadaver courses, his live-surgery experience teaching visiting doctors or residents on performing the TVT and TVT-O procedures, and his interaction with fellow surgeons at these events. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 32–33. He relied on other resources as well, including:

- his review of the published medical literature on the success and complication rates associated with the TVT and TVT-O, which includes "over 1,000 TVT studies, over 150 randomized controlled trials on TVT and TVT-O, and multiple meta-analyses" (*id*. at 33); and
- information he learned at medical conferences and professional society meetings he has regularly attended throughout his career (*id*.).

Therefore, contrary to Plaintiffs' assertion, Dr. Khandwala does not rely solely "on his own practice and experience." Am. Pls.' Mem. (Dkt. 2470) at 5.

Plaintiffs' attempt to shoehorn Dr. Khandwala's opinions into the Court's rulings in *Tyree* and *Waltman*, Am. Pls.' Mem. (Dkt. 2470) at 3–5, fails. Those cases are distinguishable. In both, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 584 (S.D.W. Va. 2014) ("The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed."); *Waltman v. Boston Sci. Corp.*, No. 2:12-CV-691, 2016 WL 3198322, at *17 (S.D.W. Va. June 8, 2016) ("without additional expertise in the specific area of product warnings, a doctor . . . is not qualified to opine that a product warning was adequate merely because it included risks he observed in his own practice").

Here, Dr. Khandwala will offer testimony that certain risks do not occur, or are not unique to pelvic mesh devices and are well known to surgeons. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 32–34. He employed a sound methodology in developing these opinions by relying upon a large pool of scientific literature and studies, combined with clinical experience, review of FDA regulations and statements, and discussions with colleagues. That Plaintiffs may disagree with Dr. Khandwala's conclusion can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

In summary, Dr. Khandwala is qualified and used a reliable methodology to support his opinions about the risks of implanting mesh and whether certain risks were common knowledge. His testimony should be admitted under *Daubert* and Rule 702.

II. Dr. Khandwala's Opinions on Biocompatibility and Mesh Physical Characteristics Are Admissible.

A. Dr. Khandwala Has the Necessary Qualifications.

Dr. Khandwala proposes to testify that TVT mesh does not fray, curl, rope, or experience particle loss (Ex. B to Am. Pls.' Mot. (Dkt. 2469-1) Khandwala TVT/TVT-O Report at 36); it does not degrade (*id*. at 36–37); it does not shrink (*id*. at 38); and it maintains its macroporous construction after implantation (*id*.). The Court concluded last month that Dr. Khandwala is qualified to testify on mesh properties. *See In re: Ethicon*, 2016 WL 4599218, at *3. It should do the same here.

Dr. Khandwala is well qualified to testify on the properties and characteristics of the mesh used in the TVT, TVT-O, and TVT-Secur. As explained, he is an accomplished urogynecologist, board certified not only in Obstetrics and Gynecology but also in the nascent specialty of FPMRS. He has extensive experience implanting these and other synthetic mesh slings, performing revision surgeries, investigating mesh slings and related products and procedures in clinical trials, publishing his findings, and training other surgeons in these procedures.

Despite these substantial qualifications, Plaintiffs wrongly argue that Dr. Khandwala is not qualified to testify about these issues because he is not a biomaterials expert, a pathologist, or a toxicologist; has not conducted bench testing on explanted mesh or polypropylene; has not published on degradation; and has not conducted studies or published on mesh porosity, flexibility, and stiffness. Am. Pls.' Mem. (Dkt. 2470) at 9–15. Contrary to Plaintiffs' argument, this Court has repeatedly allowed medical doctors with relevant clinical experience—now including Dr. Khandwala, *In re: Ethicon*, 2016 WL 4599218, at *3—to offer opinions regarding the characteristics of polypropylene. *See, e.g., Trevino v. Boston Sci. Corp.*, No. 2:13-CV-01617,

Slip Copy 2016 WL 2939521, at *44 (S.D.W. Va. May 19, 2016) (extensive clinical and teaching experience of urogynecologist Dr. Michael Douso qualifies him to testify that he has not experienced certain alleged physical properties in the defendant's devices); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction"); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 706-07, 735 (S.D.W. Va. July 8, 2014) (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree*, 54 F. Supp. 3d at 585 (rejecting similar challenge of defense expert Lonny Green, M.D.); *Jones v. C. R. Bard, Inc.*, No. 2:11–cv–00114, at 6-9 [Dkt. 391] (S.D.W. Va. Jan. 6, 2014).

Dr. Khandwala has similar experience to these experts. The Court should adopt its recent ruling that he is qualified to offer his opinions on the material properties of polypropylene.

B. Dr. Khandwala's Opinions About Mesh Characteristics Are Reliable.

In its recent ruling on Plaintiffs' challenge to Dr. Khandwala's Wave 1 opinions and testimony, the Court reserved ruling on the reliability of Dr. Khandwala's opinions regarding mesh contracture, porosity and stiffness, concluding that the Court was "without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on a doctor's clinical experience *not* observing something." *In re: Ethicon*, 2016 WL 4599218, at *3. In reaching his conclusions on mesh biocompatibility and mesh physical characteristics, however, Dr. Khandwala relied not only on his own education and clinical experience, but also on dozens of peer-reviewed scientific articles, FDA sources, and statements of the American Urogynecologic Society, American Urological Association, and National Institute of Health and Care Excellence in forming his opinions. *See* Ex. B to Am. Pls.' Mot.

(Dkt. 2469-1), Khandwala TVT/TVT-O Report at 17–33; *see also* Ex. C to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT-Secur Report at 16–27, 32–38.

While Dr. Khandwala implicitly relied on his clinical experience to describe the surgical procedures involved (*see, e.g., id*. at 18, 21), he relied on randomized clinical trials, meta-analyses, systemic reviews, and position statements of urogynecological and other associations in reaching his conclusions about mesh characteristics such as shrinkage and alleged mesh-related complications. *Id*. at 18–31. In concluding that TVT is "[t]he new gold standard," he presumably drew on his own clinical experience, but relied primarily on studies comparing the number of traditional procedures to those using synthetic slings, as well as a study evaluating the practice patterns of members of the International Urogynecological Association. *Id*. at 20–21. Similarly, in reaching his conclusions regarding laser versus mechanically cut mesh, he relied not only on his own experience but also his review of the peer-reviewed literature, which he concluded did not support Plaintiffs' theory that mechanically cut mesh experiences significant fraying, roping, curling, and particle loss. *Id*. at 31–32.

The scientific literature on which Dr. Khandwala relies includes randomized clinical trials as well as systematic reviews and meta-analyses. *See, e.g.*, Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 17–25; *see also* Ex. C to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT-Secur Report at 32–38, 46–55. "A fundamental principle of evidence-based medicine . . . is that the strength of medical evidence supporting a therapy or strategy is hierarchical. When ordered from strongest to weakest, systematic review of randomized trials (meta-analysis) is at the top, followed by single randomized trials, systematic reviews of observational studies, single observational studies, physiological studies, and unsystematic clinical observations." FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 687,

723-24 (3d ed. 2011). Dr. Khandwala's opinions are based on the highest-level scientific evidence on the subject, as well as his nearly 20 years of clinical experience with these products. His opinions are reliable, relevant, and admissible. *See, e.g.*, *Huskey*, 29 F. Supp. 3d at 735 (finding degradation-related opinions of OB/GYN reliable where they were based on expert's clinical experience and review of relevant literature demonstrating a lack of evidence of clinically significant degradation).

Plaintiffs are wrong that Dr. Khandwala's opinions regarding degradation, contraction, shrinkage, and particle loss are too "general" to be admissible. Am. Pls.' Mem. (Dkt. 2470) at 12 (citing *Tyree*, 54 F. Supp. 3d at 580–81). Plaintiffs incorrectly assert that Dr. Khandwala's opinions are inadmissible because they are based on his clinical experience, during which he has not observed mesh degradation, fraying, or migrating particles. *Id*. at 12–13 (citing statements in Dr. Khandwala's reports and deposition testimony). Contrary to Plaintiffs' intimation, these are not the *only* bases for Dr. Khandwala's opinions. As explained, they are based on his extensive literature review and the highest-quality scientific evidence. These are the type of grounds that this Court has deemed sufficiently reliable to support mesh-characteristic opinions such as those offered by Dr. Khandwala. *See Huskey*, 29 F. Supp. 3d at 735.

Plaintiffs further wrongly claim that Dr. Khandwala's opinions regarding porosity are "based on insufficient data." Am. Pls.' Mem. (Dkt. 2470) at 15 (citing Ex. D to Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 145:18–24). The quoted testimony merely establishes that Dr. Khandwala has not conducted studies of or published on porosity or weight of synthetic mesh himself. Ex. D to Am. Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 145:18–24. Plaintiffs do not address the substantial bases for Dr. Khandwala's opinions cited above, or the Court's rulings deeming comparable opinions of similarly qualified surgeons reliable. *See supra*.

Accordingly, Dr. Khandwala is qualified to provide opinions on biocompatibility and mesh physical characteristics, and supported his opinions with a reliable methodology. The Court should therefore deem his testimony admissible.

III. Dr. Khandwala Is Qualified to Testify on Design-Related Topics.

Dr. Khandwala seeks to testify that the mesh material and design of the TVT products are appropriate and that designs proposed by Plaintiffs' experts that would use other mesh are not safer alternative designs. *E.g.*, Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 29–31; Ex. C to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT-Secur Report at 70–72. Dr. Khandwala is qualified to offer these opinions based on his clinical experience and review of the medical literature. *See supra*; *see also Huskey*, 29 F. Supp. 3d at 721 (finding plaintiffs' expert urologist was "certainly fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product"). Dr. Khandwala also has direct experience with the design of related products, having submitted drawings of design modifications to a mesh system to the system's manufacturer, and having received a provisional patent on another product. Ex. 1, Khandwala 7/8/16 Dep. Tr. 68:17–70:8. And, as Plaintiffs acknowledge, Dr. Khandwala has reviewed Ethicon documents and "exhaustive studies" in the medical literature of numerous aspects of the Ethicon sling designs. Am. Pls.' Mem. (Dkt. 2470) at 17–18.[3]

[3] Plaintiffs attempt to discount this review by calculating he could only have spent "two minutes reviewing each of the documents on his reliance list." *Id*. at 18. Plaintiffs' calculation, based on the 72 hours he spent preparing his Wave 2 general report, is misleading. *See id*.; *see also* Ex. 1, Khandwala 7/8/16 Dep. Tr. 10:11–20, 13:12–16. Dr. Khandwala testified that the 72 hours did not represent the total time he had spent reviewing these materials, as he was very familiar with many of the documents in his reliance list, having reviewed them many times in the course of preparing for publication papers that he authored. *Id*. 45:5–21.

Plaintiffs assert that Dr. Khandwala is not qualified to offer opinions regarding the design of the TVT, TVT-O, or TVT-Secur because he does not have experience "designing any of the relevant devices" and because his design experience relates to implant technique rather than mesh slings themselves. Am. Pls.' Mem. (Dkt. 2470) at 15–16; *see also id.* at 17 (citing *Tyree* and *Robbins*).[4] Plaintiffs' reliance on *Tyree* and *Robbins* is misplaced. The quoted passage in *Tyree* relates to the exclusion of design opinions of urogynecologist Dr. Culligan, who could only testify to having "design preferences," rather than design experience. *Tyree*, 54 F. Supp. 3d at 581. The Court found Dr. Culligan unqualified on this topic for similar reasons in *Robbins*. *See Robbins v. Boston Sci. Corp.*, No. 2:12-CV-01413, 2016 WL 3189248, at *22 (S.D.W. Va. June 7, 2016).

Dr. Khandwala's experience is more akin to that of Dr. Ostergard, a urogynecologist who was deemed qualified to offer design-related opinion testimony because he had performed "design theory work" for a mesh device manufacturer. *Tyree*, 54 F. Supp. 3d at 581. Accordingly, the Court should deem Dr. Khandwala qualified to offer this testimony under *Daubert* and Rule 702.

[4] Plaintiffs state that "any opinions Dr. Khandwala may have regarding the design of the mesh [are] unreliable," but do not support this statement with any citations or analysis. Am. Pls.' Mem. (Dkt. 2470) at 18.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 11, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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